

CLAIMS

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1. An apparatus, comprising:
2. an expandable member being sized to be positionable in a sphincter; and
3. an energy delivery device coupled to the expandable member, the energy
4. delivery device having a configuration that controllably produces lesions of a
5. sufficient size, number and configuration in an interior of the sphincter so as to create
6. a selectable tightening of the sphincter.
 1. 2. The apparatus of claim 1, wherein the configuration of the energy
2. delivery device includes a plurality of energy delivery members distributed on a
3. surface of the expandable member.
 1. 3. The apparatus of claim 2, wherein the plurality of energy delivery
2. members are radially distributed along a surface of the energy delivery device
3. expandable member.
 1. 4. The apparatus of claim 2, wherein the plurality of energy delivery
2. members are longitudinally distributed along a surface of the expandable member.
 1. 5. The apparatus of claim 1, wherein the energy delivery device covers
2. a portion of the surface of the expandable member.
 1. 6. The apparatus of claim 2, wherein the energy delivery device covers
2. substantially all of an exterior surface of the expandable member
 1. 7. The apparatus of claim 1, wherein the expandable member is sized
2. to be positionable in a sphincter and to allow the energy delivery device to contact a
3. portion of the inner surface of a sphincter.

1 8. The apparatus of claim 1, wherein the expandable member is sized
2 to be positionable in a sphincter and to allow the energy delivery device to contact all
3 of an inner surface of the sphincter.

1 9. The apparatus of claim 1, where the energy delivery device is sized to
2 be positionable in the sphincter and non-permanently dilate the sphincter from a
3 contracted state; and
4 wherein the sphincter returns to a pretreatment contracted state upon a
5 removal of the expandable member from the sphincter.

1 10. The apparatus of claim 1, wherein the lesions are formed in a muscle
2 tissue underlying a sphincter mucosal layer.

1 11. The apparatus of claim 1, wherein the sphincter is a lower
2 esophageal sphincter.

1 12. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions at a fixed depth from a mucosal surface layer of the
3 sphincter of no more than 4 mms.

1 13. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and minimizes injury to a mucosal and a
3 submucosal layer of the sphincter.

1 14. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and reduces a frequency of sphincter relaxation.

- 1 15. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and reduces a duration of sphincter relaxation.
- 1 16. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and reduces a frequency of reflux of stomach
3 contents into an esophagus.
- 1 17. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and reduces a frequency of a symptom of reflux of
3 stomach contents into an esophagus.
- 1 18. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates the lesions and reduces an incidence of a sequela of reflux of
3 stomach contents into an esophagus.
- 1 19. The apparatus of claim 1, wherein the energy delivery device is
2 positioned on an exterior surface of the expandable member.
- 1 20. The apparatus of claim 1, wherein the energy delivery device is
2 positioned on an interior surface of the expandable member.
- 1 21. The apparatus of claim 1, further comprising:
2 a lumen positioned in an interior of the expandable member.
- 1 22. The apparatus of claim 1, wherein the expandable member is
2 expandable.
- 1 23. The apparatus of claim 1, wherein the expandable member is a
2 balloon.

- 1 24. The apparatus of claim 1, wherein the expandable member is made
2 of an expandable material.
- 1 25. The apparatus of claim 1, wherein the expandable member is made
2 of a porous material.
- 1 26. The apparatus of claim 1, further comprising:
2 an electrolytic solution housed in an expanded expandable member.
- 1 27. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device delivers energy to promote a fibroblast cell infiltration at a site of the
3 lesions.
- 1 28. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device delivers energy to promote a fibroblast growth at a site of the lesions.
- 1 29. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device delivers energy that promotes a myofibroblast cell infiltration at a site
3 of the lesions.
- 1 30. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates a tightening of a lower esophageal sphincter without
3 permanently damaging anatomical structures near the lower esophageal sphincter.
- 1 31. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates a tightening of the lower esophageal sphincter without
3 permanently damaging an aorta positioned near the lower esophageal sphincter.

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1 32. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates a tightening of the lower esophageal sphincter without
3 permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

1 33. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates a tightening of the lower esophageal sphincter without
3 permanently damaging an esophageal plexus of nerves and veins positioned near the
4 lower esophageal sphincter.

1 34. The apparatus of claim 1, wherein the configuration of the energy
2 delivery device creates a tightening of the lower esophageal sphincter while preserving
3 a blood supply to the lower esophageal sphincter.

1 35. The apparatus of claim 1, wherein the energy delivery device is an
2 RF electrode.

1 36. The apparatus of claim 35, further comprising:
2 an RF energy source coupled to the RF electrode.

1 37. The apparatus of claim 1, wherein the energy delivery device is a
2 microwave antenna.

1 38. The apparatus of claim 37, further comprising:
2 a microwave energy source coupled to the microwave antenna.

1 39. The apparatus of claim 1, wherein the energy delivery device is a
2 waveguide.

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- 1 40. The apparatus of claim 39, further comprising:
2 a light source coupled to the waveguide.
- 1 41. The apparatus of claim 40, wherein the light source is a laser.
- 1 42. The apparatus of claim 1, wherein the energy delivery device is an
2 acoustical transducer.
- 1 43. The apparatus of claim 1, wherein the energy delivery device is a
2 resistive heating device.
- 1 44. The apparatus of claim 1, further comprising:
2 a visualization device coupled to the expandable member.
- 1 45. The apparatus of claim 1, further comprising:
2 an extension member coupled to the expandable member.
- 1 46. The apparatus of claim 45, wherein a proximal portion of the
2 extension member is maneuverable by a medical practitioner.
- 1 47. The apparatus of claim 1, wherein the energy delivery device is a
2 plurality of RF electrodes.
- 1 48. The apparatus of claim 47, wherein the plurality of electrodes is a
2 flexible circuit.
- 1 49. The apparatus of claim 1, further comprising:
2 a mechanical expansion device coupled to the expandable member.

1 50. An apparatus, comprising:
2 an expandable member means sized to be positionable in a lower esophageal
3 sphincter and non-permanently dilate the lower esophageal sphincter from a
4 contracted state;

5 an energy delivery device means coupled to the expandable member means,
6 the energy delivery device means having a configuration that controllably produces
7 lesions of a sufficient size, number and configuration in an interior of the lower
8 esophageal sphincter to create a tightening of the lower esophageal sphincter; and,
9 wherein the lower esophageal sphincter returns to a contracted state upon a
10 removal of the expandable member means from the sphincter.

1 51. The apparatus of claim 50, wherein the energy delivery device means
2 has a configuration that controllably produces lesions an interior of the lower
3 esophageal sphincter without creating a permanent impairment of the lower
4 esophageal sphincter's ability to achieve a physiologically normal state of closure.

1 52. The apparatus of claim 50, wherein the energy delivery device is
2 positioned on an exterior surface of the expandable member means.

1 53. The apparatus of claim 50, wherein the energy delivery device is
2 positioned on an interior surface of the expandable member means.

1 54. The apparatus of claim 50, further comprising:
2 a lumen means positioned in an interior of the expandable member means.

1 55. The apparatus of claim 50, wherein the expandable member means is
2 expandable.

1 56. The apparatus of claim 50, wherein the expandable member means is
2 a balloon.

1 57. The apparatus of claim 50, wherein the expandable member means is
2 made of an expandable material.

1 58. The apparatus of claim 50, wherein the expandable member means is
2 made of a porous material.

1 59. The apparatus of claim 57, further comprising:
2 an electrolytic solution means housed in an expanded expandable member
3 means.

1 60. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means delivers energy to the interior of the lower esophageal sphincter
3 and creates a fibroblast proliferation in the interior of the lower esophageal sphincter.

1 61. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means delivers energy to the interior of the lower esophageal
3 sphincter and creates a myofibroblast proliferation in the lower esophageal sphincter.

1 62. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means creates a tightening of the lower esophageal sphincter without
3 permanently disrupting an aorta positioned near the lower esophageal sphincter.

1 63. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means creates a tightening of the lower esophageal sphincter without
3 permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

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1 64. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means creates a tightening of the lower esophageal sphincter without
3 permanently damaging an esophageal plexus of nerves and veins positioned near the
4 lower esophageal sphincter.

1 65. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means creates a tightening of the lower esophageal sphincter while
3 preserving a blood supply to the lower esophageal sphincter.

1 66. The apparatus of claim 50, wherein the configuration of the energy
2 delivery device means creates a tightening of the lower esophageal sphincter while
3 creating submucosal lesions in the lower esophageal sphincter.

1 67. The apparatus of claim 50, wherein the energy delivery device means
2 is an RF electrode means.

1 68. The apparatus of claim 47, further comprising:
2 an RF energy source means coupled to the RF electrode means.

1 69. The apparatus of claim 50, wherein the energy delivery device means
2 is a microwave antenna means.

1 70. The apparatus of claim 69, further comprising:
2 a microwave energy source means coupled to the microwave antenna means.

1 71. The apparatus of claim 50, wherein the energy delivery device means
2 is a waveguide means.

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1 72. The apparatus of claim 71, further comprising:
2 a light source means coupled to the waveguide means.

1 73. The apparatus of claim 72, wherein the light source means is a laser
2 means.

1 74. The apparatus of claim 50, wherein the energy delivery device means
2 is an acoustical transducer means.

1 75. The apparatus of claim 74, further comprising:
2 an acoustical energy source means coupled to the acoustical transducer
3 means.

1 76. The apparatus of claim 50, wherein the energy delivery device means
2 is a resistive heating device means.

1 77. The apparatus of claim 50, further comprising:
2 a visualization device means coupled to the expandable member means.

1 78. The apparatus of claim 50, further comprising:
2 a extension member means coupled to the expandable member means.

1 79. The apparatus of claim 78, wherein a proximal portion of the
2 extension member means is maneuverable by a medical practitioner.

1 80. The apparatus of claim 50, wherein the energy delivery device means
2 is a plurality of RF electrode means.

1 81. The apparatus of claim 80, wherein the plurality of electrode means
2 is a flexible circuit means.

1 82. The apparatus of claim 50, further comprising:
2 a mechanical expansion device means coupled to the expandable member
3 means.

1 83. A method of treating a sphincter, comprising:
2 providing an expandable member sized to be positionable in the sphincter and
3 configured to non-permanently open the sphincter from a contracted configuration,
4 and an energy delivery device coupled to the expandable member;
5 introducing the expandable member in the sphincter;
6 dilating the sphincter from the contracted state;
7 delivering sufficient energy from the energy source to the sphincter to tighten
8 the sphincter; and
9 removing the expandable member from the sphincter.

1 84. The method of claim 83, wherein the energy delivery device has a
2 configuration that controllably produces lesions an interior of the sphincter without
3 creating a permanent impairment of the sphincter's ability to achieve a physiologically
4 normal state of closure.

1 85. The method of claim 83, wherein energy delivery device delivers
2 sufficient energy to cause a proliferation of fibroblast cells in the sphincter.

1 86. The method of claim 85, wherein the energy delivery device delivers
2 sufficient energy to cause a proliferation of myofibroblast cells in the sphincter.

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1 87. The method of claim 83, wherein the energy delivery device delivers
2 sufficient energy to create a tightening of the sphincter without permanently damaging
3 anatomical structures near the sphincter.

1 88. The method of claim 87, wherein the energy delivery device delivers
2 sufficient energy to create a tightening of the sphincter without permanently
3 disrupting an aorta positioned near the sphincter.

1 89. The method of claim 87, wherein the energy delivery device delivers
2 a sufficient amount of energy to create a tightening of the lower esophageal sphincter
3 without permanently damaging a vagus nerve positioned near the sphincter.

1 90. The method of claim 87, wherein the energy delivery device delivers
2 a sufficient amount of energy to create a tightening of the lower esophageal sphincter
3 without permanently damaging an esophageal plexus of nerves and veins positioned
4 near the sphincter.

1 91. The method of claim 87, wherein the energy delivery device delivers
2 a sufficient amount of energy to create a tightening of the lower esophageal sphincter
3 while preserving a blood supply to the sphincter.

1 92. The method of claim 83, wherein the energy delivery device creates
2 a tightening of the lower esophageal sphincter while creating submucosal lesions in
3 the sphincter.

1 93. The method of claim 83, wherein the expandable member is
2 expandable.

1 94. The method of claim 73, wherein the expandable member is
2 introduced in the lower esophageal sphincter in an unexpanded state.

1 95. The method of claim 94, wherein the expandable member is
2 expanded to an expanded state when positioned in the sphincter.

1 96. The method of claim 93, wherein the expandable member is a
2 balloon.

1 97. The method of claim 93, further comprising:
2 an electrolytic solution housed in an expanded expandable member.

1 98. The method of claim 83, wherein the energy delivery device is an RF
2 electrode.

1 99. The method of claim 98, further comprising:
2 an RF energy source coupled to the RF electrode.

1 100. The method of claim 83, wherein the energy delivery device is a
2 microwave antenna.

1 101. The method of claim 100, further comprising:
2 a microwave energy source coupled to the microwave antenna.

1 102. The method of claim 83, wherein the energy delivery device is a
2 waveguide.

1 103. The method of claim 102, further comprising:

2 a light source coupled to the waveguide.

1 104. The method of claim 83, wherein the light source is a laser.

1 105. The method of claim 83, wherein the energy delivery device is an
2 acoustical transducer.

1 106. The method of claim 105, further comprising:
2 an acoustical energy source coupled to the acoustical transducer.

1 107. The method of claim 83, wherein the energy delivery device is a
2 resistive heating device.

1 108. The method of claim 83, wherein the energy delivery device is
2 delivered to the sphincter transorally without an endoscope.

1 109. The method of claim 83, wherein the energy delivery device is
2 delivered to the sphincter with an endoscope.

1 110. The method of claim 83, wherein the sphincter is the lower
2 esophageal sphincter.